DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 4, 2015

OptoMedical Technologies GmbH
c/o Mr. Richard A. Vincins, CQA, CBA RAC (US, EU)
Vice President, Quality Assurance
Emergo Global Consulting Group
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K142953
Trade/Device Name: OCT-Camera, Model 21101A1
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope, AC-Powered
Regulatory Class: Class II
Product Code: HLI, OBO
Dated: January 27, 2015
Received: January 29, 2015

Dear Mr. Vincins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose, and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142953

Device Name
OCT-Camera

Indications for Use *(Describe)*
OptoMedical Technologies OCT-Camera is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SD-OCT). The OCT-Camera is indicated for the use as an aid in the diagnosis of physiologic and pathologic conditions of the eye through non-contact optical imaging. Imaging of the various tissues of the eye is supported through the use of interchangeable lenses. It is indicated for use on patient populations from premature and neonatal infants to adult, and is suitable for patients ambulatory or confined. The system is indicated for use in supine imaging, mounted to a surgical microscope HS Hi-R NEO 900A NIR (Haag-Streit), and is suited for imaging patients under anesthesia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

for

OCT-Camera

K142953

1. Submission Sponsor

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GERMANY
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Fax: 0049 451 2903 333
Contact: Alexander HOLZHEY, Quality and Regulatory Affairs Manager

2. Submission Correspondent

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Email: project.management@emergogroup.com

3. Date Prepared

2 March 2015

4. Device Identification

Trade/Proprietary Name:	OCT-Camera
Common/Usual Name:	intraoperative Optical Coherence Tomography (iOCT)
Classification Name:	Ophthalmoscope, AC-powered; Tomography, Optical Coherence
Classification Regulation:	886.1570
Product Code:	HLI, OBO
Device Class:	Class II
Classification Panel:	Ophthalmic

5. Predicate Device

Device trade name: Envisu™ SDOIS
Manufacturer name: Bioptigen Inc.
510(k) number: K120057

6. Device Description

The OCT-Camera can be attached to the camera port of surgical microscopes. The OCT-Camera is completely integrated into the surgical procedure by enabling the OCT imaging before, during, and after microsurgery without disrupting the microscopic view. The individual steps and the outcome of the surgical procedures, such as transplantation of the thin membranes or micro implants, are visualized in real time.
The OCT-Camera by OptoMedical Technologies GmbH facilitates the intraoperative use of OCT (iOCT). It is called OCT-Camera because it can be attached to the camera port of an operating microscope like any common camera that are used for the purpose of providing live view images of the surgical field.

7. Indication for Use Statement

OptoMedical Technologies OCT-Camera is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SD-OCT). The OCT-Camera is indicated for the use as an aid in the diagnosis of physiologic and pathologic conditions of the eye through non-contact optical imaging. Imaging of the various tissues of the eye is supported through the use of interchangeable lenses. It is indicated for use on patient populations from premature and neonatal infants to adult, and is suitable for patients ambulatory or confined. The system is indicated for use in supine imaging, mounted to a surgical microscope HS Hi-R NEO 900A NIR (Haag-Streit), and is suited for imaging patients under anesthesia.

8. Substantial Equivalence Discussion

The following table compares the OCT-Camera to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**OptoMedical Technologies GmbH**	**Bioptigen**	**Significant Differences**
Trade Name	OCT-Camera (subject)	SDOIS Envisu (predicate)	
510(k) Number	N/A	K120057	Same
Product Code	HLI, OBO	HLI, OBO	Same
Regulation Number	21 CFR 886.1570	21 CFR 886.1570	Same

Manufacturer	**OptoMedical Technologies GmbH**	**Bioptigen**	**Significant Differences**
Trade Name	OCT-Camera (subject)	SDOIS Envisu (predicate)	
Regulation Name	Ophthalmoscope	Ophthalmoscope	Same
Indications for Use	OptoMedical Technologies OCT-Camera is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SD-OCT). The OCT-Camera is indicated for the use as an aid in the diagnosis of physiologic and pathologic conditions of the eye through non-contact optical imaging. Imaging of the various tissues of the eye is supported through the use of interchangeable lenses. It is indicated for use on patient populations from premature and neonatal infants to adult, and is suitable for patients ambulatory or confined. The system is indicated for use in supine imaging, mounted to a surgical microscope HS Hi-R NEO 900A NIR (Haag-Streit), and is suited for imaging patients under anesthesia.	Bioptigen Envisu™ SDOIS is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SD-OCT). The Envisu™ SDOIS is indicated for the use as an aid in the diagnosis of physiologic and pathologic conditions of the eye through non-contact optical imaging. Imaging of the various tissues of the eye is supported through the use of interchangeable lenses. It is indicated for use on patient populations from premature and neonatal infants to adult, and is suitable for patients ambulatory or confined. The system is indicated for use in upright or supine imaging, handheld or mounted, and is suited for imaging patients under anesthesia.	Similar
Method of Operation	SD-OCT	SD-OCT	Same
Light Source	SLED	SLED	Same
Light Source Classification	Class 1 LED	Class 1 LED	Same
Optical Power (OCT Light)	≤2350 µW at cornea during OCT scan ≤47 µW at cornea without scanning Complies with the requirements of IEC 60825-1:2007, Part 1 and 2	≤750 µW at cornea	Similar
Optical Power (Pilot Light)	<50 µW at cornea	-option not available-	Similar
Resolution, Lateral	Retina: 10.6 to 74 µm in tissue, dependent on magnification of microscope and its retina lens Anterior Segment: 10.6 to 37 µm, dependent on magnification of microscope	Retina: 20 µm in tissue Anterior Segment: 9, 12 and 25 µm	Similar

Manufacturer	OptoMedical Technologies GmbH	Bioptigen	Significant Differences
Trade Name	OCT-Camera (subject)	SDOIS Envisu (predicate)	
Resolution, Axial	≤ 7.5 µm in tissue	≤ 6 µm in tissue	Similar
Depth Range (in tissue/in air)	3.1 / 4.2 mm	1.7 / 2.3 mm	Similar
Scanner Type	Galvanometric Mirror Pair	Galvanometric Mirror Pair	same
Scan Patterns	Line, rectangular volume	Line, rectangular volume, circle, concentric rings, radial lines	Similar
Scan Pixels	Axial (depth): 1024 Lateral: fixed to 1,000 A-Scans/B-Scan Max. 30,000 total A-Scans/Volume-Scan	Axial (depth): 512 or 1024 Lateral: User Selectable Max. 5,000 A-Scans/B-Scan Max. 150,000 total A-Scans	Similar
Scan Rate	15,000 A-Scans/s	32,000 A-Scans/s	Similar
Detection	Transmission Grating, Spectrometer / Line Scan Camera	Transmission Grating, Spectrometer / Line Scan Camera	Same
Scanner Ergonomics	Mounted to camera port of a surgical microscope	Mounted (tabletop) or Handheld	Similar
Patient Interface	Not required	Optional Chin Rest Assembly	Similar
Operating System	Win XP	Win XP	Similar
Processor	2.66 GHz Dual Core	Dual 2.0 GHz Quad Core	Similar
Memory	4 GB	4 GB	same
AC Powered	Yes	Yes	Same
Battery Operated	No	No	Similar
Electrical Safety Testing Passed	IEC 60601-1, EN 60601-1-2	IEC 60601-1, EN 60601-1-2	Same

9. Non-Clinical Performance Data

The OCT-Camara mets all the requirements for overall design, performance and electrical safety confirms that the output meets the design inputs and specifications. The OCT-Camara passed all testing and supports the claims of substantial equivalence and safe operation.

The OCT-Camera complies with the applicable voluntary standards for light hazard protection and safe laser products. The device passed all the testing in accordance with national and international standards.

In the following please find a listing of testing performed at OptoMedical Technologies GmbH all of which have been passed positively to demonstrate safety and effectiveness.

The following testing has been performed to support substantial equivalence:

- IEC 60601-1: 2005 *Medical electrical equipment – Part 1-2, General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*
- IEC 60601-1-2: 2007 *Medical electrical equipment – Part 1-2, General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*
- ISO 14971: 2007 *Medical devices -- Application of risk management to medical devices*
- IEC 60825-1: 2007 *Safety of laser products - Part 1: Equipment classification and requirements*
- ISO 15004-2: 2007 *Ophthalmic instruments -- Fundamental requirements and test methods -- Part 2: Light hazard protection*

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the OCT-Camera and the predicate devices do not raise any questions regarding its safety and effectiveness. The OCT-Camera, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.